UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

LOIS ANNETTE ANASTASI,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 4:14CV00053 ERW
	)	
WRIGHT MEDICAL TECHNOLOGY, INC., and WRIGHT MEDICAL GROUP, INC.,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

This matter comes before the Court on "Defendants Wright Medical Technology, Inc. and Wright Medical Group, Inc.'s Motion to Dismiss Counts I, VI, VII, and VIII of Plaintiff's Complaint" [ECF No. 5].

I. BACKGROUND

On January 13, 2014, Plaintiff Lois Annette Anastasi, pursuant to 28 U.S.C. § 1332(a)(1), filed a Complaint against Defendants Wright Medical Technology, Inc., and Wright Medical Group, Inc. (collectively referred to as "Defendants"), alleging injuries related to medical devices, known as the Wright Medical Hip Implant and Conserve Cup, implanted in her hip [ECF No. 1]. Plaintiff's Complaint asserts eight counts: I) strict liability (design defect); II) strict liability (manufacturing defect); III) strict liability (failure to warn); IV) negligence; V) negligent misrepresentation; VI) fraudulent misrepresentation; VII) breach of express warranty; and VIII) breach of implied warranty.

Defendants filed their Motion to Dismiss Counts I, VI, VII, and VIII of Plaintiff's Complaint on March 14, 2014 [ECF No. 5]. Plaintiff filed a Memorandum in Opposition [ECF No. 11]. As an initial matter, the Court notes Plaintiff concedes the dismissal of Counts VII and

VIII from her Complaint. Accordingly, the Court shall dismiss those two counts, in their entirety; and its analysis of Defendants' Motion to Dismiss shall be limited to a discussion of their arguments regarding Counts I and VI.

II. LEGAL STANDARD

A party may move under Rule 12(b)(6) to dismiss a complaint for "fail[ing] to state a claim upon which relief may be granted." Fed. R. Civ. P. 12(b)(6). The purpose of a motion to dismiss is to test "the sufficiency of a complaint[.]" *M.M. Silta, Inc. v. Cleveland Cliffs, Inc.*, 616 F.3d 872, 876 (8th Cir. 2010).

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal quotations and citation omitted). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* Ordinarily, only the facts alleged in the complaint are considered for purposes of a motion to dismiss; however, materials attached to the complaint may also be considered in construing its sufficiency. *Reynolds v. Dormire*, 636 F.3d 976, 979 (8th Cir. 2011).

When ruling on a motion to dismiss, a court "must liberally construe a complaint in favor of the plaintiff[.]" *Huggins v. FedEx Ground Package Sys., Inc.*, 592 F.3d 853, 862 (8th Cir. 2010). However, if a claim fails to allege one of the elements necessary to recovery on a legal theory, that claim must be dismissed for failure to state a claim upon which relief can be granted. *Crest Constr. II, Inc. v. Doe*, 660 F.3d 346, 355 (8th Cir. 2011). "Threadbare recitals of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678; *Bell Atlantic v. Twombly*, 550 U.S. 544, 555 (2007). Although courts must accept all factual

allegations as true, they are not bound to take as true "a legal conclusion couched as a factual allegation." *Twombly*, 550 U.S. at 555 (internal quotations and citation omitted); *Iqbal*, 556 U.S. at 677-78.

III. STATEMENT OF FACTS

For purposes of this Motion to Dismiss, the following pertinent facts, as alleged in Plaintiffs Amended Complaint and contained in exhibits incorporated therein, are accepted as true.

At all relevant times, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the metal-on-metal Wright Hip Implant including the Conserve Cup.

The hip joint, where the femur connects to the pelvis, is made up of the femoral head and acetabulum (a cup-like structure at the bottom of the pelvis). The femoral head, a ball-like structure at the top of the femur, rotates within the acetabulum. A total hip replacement replaces the body's natural hip joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: a femoral stem; a femoral head; a liner; and an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the liner and acetabular shell. These conventional hip replacement implants typically last 15 to 20 years.

The Wright Conserve Cup has a different design, one that puts the metal femoral ball directly in contact with a metal acetabular cup; most other hip replacements use a polyethylene or plastic acetabular cup. By using a metal acetabular cup and a metal femoral ball, the Wright

Conserve Cup forces metal to rub against metal with the full weight and pressure of the human body.

On or about January 11, 2012, Plaintiff underwent a right total hip replacement at St. David's Georgetown Hospital in Georgetown, Texas. Dr. Clifton O'Meara performed the procedure. During that procedure, the following hip implant components manufactured and marketed by Defendants were implanted into Plaintiff's body: Wright Medical Total A-Class Head (Size 38 mm, Ref. No. 38AM-3804, Lot No. 03010738491401); Wright Medical Profemur Plasma Z Stem (size 3, Ref. No. PHA-00264, Lot No. 0511349140); Wright Medical Profemur Modular Neck (Size 8, Ref. No. PHAC-1252, Lot No. 0211188740); and Wright Dynasty CoCr Liner (Size 38mm, Ref. No. DLCOGD38, Lot No. 019752153). The Wright Medical Hip Implant with the Conserve Cup that were implanted into Plaintiff had not been materially altered or modified prior to the implantation of the devices.

Subsequently, Plaintiff experienced severe and debilitating pain, discomfort, and inflammation in her right thigh and right hip area; severe infection in her hip caused by metallosis; and loosening of the Wright Medical Hip Implant and Conserve Cup. On or about May 1, 2013, Plaintiff had the Wright Medical Device on her right hip explanted at St. David's Georgetown Hospital in Georgetown, Texas. Dr. O'Meara performed the procedure. Because of Defendants' defective design for the Wright Conserve Cup, hundreds of patients, including Plaintiff, have been forced to undergo surgeries to replace the failed hip implants within only a few years after being implanted with the defective Wright Medical Hip Implant.

The design of the Wright Medical Hip Implant, including the Conserve Cup, was not sufficiently tested by Defendants, and the Conserve Cup was never approved by the FDA as being safe or effective for the product's intended purpose.

The Conserve Cup is a class III medical device. Class III devices are those devices that operate to sustain human life, or are for a use substantially important in preventing impairment of human health, or pose potentially unreasonable risks to patients. The Medical Device Amendments to the Food, Drug and Cosmetics Act of 1938 ("MDA") require Class III medical devices, including the Wright Medical Hip Implant and the Conserve Cup, to undergo premarket approval by the Food and Drug Administration ("FDA"), a process that obligates the manufacturer to design and implement a clinical investigation and to submit the results of that investigation to the FDA as part of obtaining approval to sell the device.

Premarket approval is a rigorous process, requiring manufacturers to submit a multi-volume application that includes, among other things: full reports of all studies and investigations of the device's safety and effectiveness that have been published or reasonably should be known to the applicant; a full statement of the device's components, ingredients, and properties or principle of operation; a listing of the facilities used in, and a full description of the methods and controls used for the manufacture, processing, and, when relevant, packing installation of such device; samples of device components as required by the FDA; and a specimen of the proposed labeling. The FDA may grant premarket approval only if it finds there is reasonable assurance that a particular medical device is safe and effective, and the FDA must weigh any probable benefit to health stemming from use of the device against any probable risk of injury or illness emanating from such use.

A medical device that was on the market prior to the effective date of the MDA (i.e., a device that was approved prior to May 28, 1976), referred to as "grandfathered" device, was not required to undergo premarket approval. In addition, a medical device marketed after the MDA's effective date may bypass the rigorous premarket approval process if the device is "substantially

equivalent" to a grandfathered pre-MDA device. This exception to premarket approval is known as the "510(k)" process and simply requires a manufacturer to notify the FDA, under section 510(k) of the MDA, of that manufacturer's intent to market a new device at least 90 days prior to the device's introduction to the market and to explain how the new device is "substantially equivalent" to a pre-MDA predicate device. The FDA may then approve the new devise for sale in the United States. Most new Class III devices in the market go through the 510(k) process.

Instead of ensuring the safety of the Conserve Cup and the Wright Medical Hip Implant through clinical trials, Defendants sought to market their Wright Medical Hip Implant, including the Conserve Cup, without conducting any clinical trials, by obtaining FDA approval under section 510(k). By telling the FDA that the Conserve Cup's design was substantially equivalent to other hip products on the market, Defendants were able to avoid the safety reviews, including clinical trials, required for pre-market approval under FDA regulations.

The FDA ultimately approved the marketing of the Wright Medical Hip Implant, including the Conserve Cup, based upon the abbreviated 510(k) process. The FDA approval, through the 510(k) process, means only that the device was substantially equivalent to another product on the market and does not mean the FDA has found the device to be safe and effective for its intended use in patients, including Plaintiff.

Under section 510(h) of 21 U.S.C. § 351, Defendants' Wright Medical Hip Implant and Conserve Cup are adulterated devices, because, among other things, the products fail to meet established performance standards, in that the products caused severe injuries to recipients of the Wright Hip Implant, and other conditions that often require premature, painful revision surgery and make future revision surgeries less likely to be successful. In addition, Defendants' Wright Medical Hip Implant and Conserve Cup are misbranded, because, among other things, they cause

severe injuries to the device recipients when they are used in the manner prescribed, recommended, or suggested in their labeling.

Implantation of Defendants' Wright Medical Hip Implant, including the Conserve Cup, results in the release of high levels of toxic metal ions into every hip implant patient's tissue and blood stream. Particles released by friction of the metal-on-metal surfaces also result in metallosis, tissue death, and tumor growth. This friction wear, commonly referred to as "edge wear" or "edge loading," is especially pronounced in the early "wear in" period, especially on the leading edge of the metal acetabular cup of the Wright Medical Hip Implant. Once the body is exposed to the Wright Medical Hip Implant and absorbs the toxic metallic ions and particular debris created by friction of the metal-on-metal implant surfaces, inflammation occurs, which leads to severe pain, infection, death of the surrounding tissue, bone loss, and the potential for tumors to develop.

Defendants' Wright Medical Hip Implant is also defective in that, as a result of the product's defective design, proper and successful surgical placement is exceedingly difficult for even experienced and competent surgeons to accomplish in implanting the devices in patients. It is estimated that perhaps only 5% of Class III medical device failures are ever reported to the FDA. Despite this fact, the FDA has received adverse event reports from patients, surgeons, and device manufacturers documenting hundreds of patient injuries attributable to metal-on-metal hip implants, including the Wright Medical Hip Implant with the Conserve Cup. These adverse event reports include a number of patient injuries, such as metallosis, premature device failure, dislocation, disarticulation, disassembly, pseudo-tumor formation, elevated cobalt and chromium levels in serum, and heavy metal toxicity. Leading orthopedic surgeons in the United States have virtually stopped using metal-on-metal hip implants, because a significant number of patients

who receive these implants suffer early failure of the implants, dislocations, and disarticulations. Many patients also suffer severe tissue loss, infection, and irreversible bone damage caused by the failure of the metal-on-metal hip implants, metallosis, presence of metallic debris in the joint space, and heavy toxicity.

In a press release issued on August 25, 2005, and published on Defendants' website, Defendants noted:

> Wright Medical Group, Inc. (NASDAZ: WMGI), a global orthopedic medical device company, today announced the launch of its wear-reducing A-Class™ Advanced Metal for use with the Company's BFH® hip technology featuring large femoral heads for increased range of motion and a lowered potential for dislocation. The new A-Class™ Advanced Metal is the result of a patent-pending process developed to reduce the creation of material debris in metal-on-metal total hip arthroplasty, significantly enhancing the cutting-edge design features of Wright's total hip systems that feature BFH® technology. Metal-on-metal articulation in hip systems for its high level of durability through reduced wear. A-Class™ Advanced Metal focuses on further minimizing wear debris, thereby potentially reducing the creation of metal ions. Wright's A-Class™ Advanced Metal minimizes wear to optimize durability, reducing the surface run-in wear to one-tenth the rate experienced by conventional total hip systems with BFH® Technology, while reducing cumulative lifetime wear by more than two-thirds.

Since 2006, Defendants have had actual knowledge that the Wright Medical Hip Implant, including the Conserve Cup, could fail early due to metal debris, thereby giving rise to unnecessary pain and suffering, debilitation, and the need for revision surgery to replace the defective implants with the attendant risk of complications and death from such further implant revision surgery in patients, including Plaintiff. In May of 2011, the FDA demanded that medical device companies who manufactured and delivered metal-on-metal hip implants conduct post-marketing studies regarding the safety of metal-on-metal implants and concerns about heavy metal poisoning in implanted patients.

Defendants have known for years that implantation of their Wright Medical Hip Implants including the Conserve Cup, results in metallosis, biological toxicity, and an increased risk for

early and excessive premature failures of the implanted devices. Defendants failed to disclose this fact to consumers, including Plaintiff. Instead, Defendants took affirmative steps to prevent physicians and consumers from learning of this fact, while aggressively marketing the Wright Medical Hip Implant and Conserve Cup as being safe and effective for use in hip replacement surgeries. This concealment was done by Defendants with the intent to induce Plaintiff, as well as other patients, and physicians, to purchase the Wright Medical Hip Implant and the Conserve Cup, and to prevent patients from discovering they had been implanted with a defective Wright Medical Hip Implant and from filing lawsuits seeking damages.

As early as March of 2006, Defendants advertised on their website and in their product brochures distributed to physicians and patients, that Defendants' Wright Medical Implant and Conserve Cup were designed to be an improvement over the metal-on-polyethylene implants, because the metal-on-metal design would reduce the amount of wear particles. In particular, Defendants' advertisements and representations included this statement: "Despite improvements in the manufacturing, processing, and sterilization of polyethylene, wear related problems still exist in modern Total Hip Arthroplasty. To address problem, the CONSERVE Total Hip System has eliminated polyethylene from the design altogether. The result is a one-piece, highly super finished metal-on-metal design, which provides significantly less wear particles than the conventional total hip replacement."

Defendants' advertisements and representations also included information that would lead patients and their surgeons to believe there would be only a minimal amount of wear debris generated from the Wright Medical Hip Implants and Conserve Cup, and the amount of wear debris would be substantially less than that associated with ceramic-on-polyethylene or cobalt chrome-on-polyethylene implant designs.

Plaintiff's physicians communicated Defendants' representations to the Plaintiff. These representations about the extended durability of the Wright Medical Hip Implant and Conserve Cup led Plaintiff and her surgeons to believe the Wright Medical Hip Implant and Conserve Cup would last longer than the approximate 15 to 20 years that a conventional hip implant would last.

Defendants made representations, affirmations of fact, or promises through Defendants' advertisements, labeling, detailing, marketing, and promotion of the Wright Medical Hip Implant and Conserve Cup to healthcare professionals, the FDA. Plaintiff, and the public, by representing the Wright Medical Implant and Conserve Cup were safe, effective, and fit and proper for their intended uses, in order to induce patients and surgeons to purchase or use the Wright Medical Hip Implant and Conserve Cup. These representations, affirmations, or promises regarding the Wright Medical Hip Implants were false. Plaintiff, in privity with Defendants through her surgeon acting as an agent, relied on Defendants' representations in choosing to purchase the Wright Medical Hip Implant and Conserve Cup.

Plaintiff and her physicians might have been able to discover the cause of Plaintiff's pain and disability, or defects in the Wright Medical Hip Implant earlier, but for the Defendants' active concealment of these facts from physicians, patients, and Plaintiff, which led to a delay in discovery and unnecessary suffering for Plaintiff.

In reliance on Defendants' concealment, Plaintiff purchased the Wright Medical Hip Implant so that her physician could surgically implant the device into Plaintiff. Had Plaintiff known the Wright Medical Hip Implant with the Conserve Cup could fail early, thereby giving rise to unnecessary physical injury, pain and suffering, debilitation, and the need for revision surgery with attendant risks of complications and death, Plaintiff would not have purchased the Wright Medical Hip Implant with the Conserve Cup.

IV. DISCUSSION

Plaintiff is a citizen and resident of Texas, and the relevant events underlying Plaintiffs' claims, including her original hip replacement and revision surgeries, occurred in Texas. Both parties agree that Texas law applies to the substantive issues in this dispute.

As relevant to this discussion, Defendants, pursuant to Federal Rule of Civil Procedure 12(b)(6), move the Court to dismiss Counts I and VI of Plaintiffs' Complaint, for failure to state a claim upon which relief may be granted [ECF Nos. 5, 6].

A. Count I – Strict Liability (Design Defect)

Defendants contend Plaintiffs' claim for design defect (Count I) should be dismissed because it is barred by Comment k to Section 402A of the Restatement (Second) of Torts. Comment k defines "unavoidably unsafe products," and reads, in pertinent part:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . .. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician . . .. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending to their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Comment k to § 402A Rest. (2d) Torts. Defendants acknowledge that Texas courts have applied Comment k to prescription drugs, but not to medical devices. However, they contend courts nationwide have adopted Comment k's reasoning regarding the field of prescription drugs and applied Comment k to bar liability in medical device design claims. Defendants assert Comment k applies here, because the hip implant components are medical devices prescribed and implanted by a physician with the intention of correcting Plaintiff's improperly functioning right

hip. They argue, to hold them strictly liable for any alleged design defect of such components, would contradict the strong public policy encouraging developments in medical treatment.

In her Memorandum in Opposition to Defendants' Motion to Dismiss, Plaintiff notes Defendants' challenge is not to the sufficiency of the Complaint's strict-liability, design-defect pleading generally, but rather, is an assertion Plaintiff cannot, as a matter of law, state such a claim for the hip implant components pursuant to Comment k [ECF No. 11]. Plaintiff first points to the lack of Texas precedent applying Comment k to medical devices. Plaintiff also contends Defendants' Comment k argument is inapplicable, at least at this juncture of the proceeding. She argues that Comment k is generally recognized as an affirmative defense, which would require Defendants to present proof the product was incapable of being made safer at the time of manufacture and distribution, and she contends their burden of proof is not excused by the FDA approval process that enabled them to introduce the device into commerce. Plaintiff claims the FDA approval process for a prescription drug is drastically different than the FDA's "Section 510(k)" (referring to the corresponding section of the original MDA) approval for "Class III"[1] medical devices such as the hip implant at issue. Section 510(k) approval refers to a limited form of review, imposed on medical device manufacturers intending to market a new device, that requires the manufacturers to submit a pre-market notification to the FDA for Class III medical devices that are the substantial equivalent of products available prior to the effective date of the MDA. Plaintiff contends, "Given the Section 510(k) approval at issue, there is no

[1]In accordance with 21 U.S.C. § 360(k), the FDA requires medical device manufacturers to submit a report before marketing a new product, indicating the class in which the device is classified under 21 U.S.C. § 360c, i.e., Class I, Class II, or Class III. Class III devices are those for which insufficient information exists to determine the adequacy of general controls, and those "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or presenting "a potential unreasonable risk or illness or injury." 21 U.S.C. § 360c(a)(1)(C).

basis for any type of judicial finding that, as a matter of law at the pleading stage, the product was 'unavoidably unsafe,'" and again, she emphasizes the lack of Texas law supporting such a result.

The duty of a federal court exercising diversity jurisdiction, when the state courts have not supplied an answer to the specific issue presented, is to apply the rule it believes would be applied by the highest court of the state if the specific question were presented to it. *Cont'l Cas. Co. v. Advance Terrazzo & Tile Co., Inc.*, 462 F.3d 1002, 1007 (8th Cir. 2006). Texas has approved the theory of strict products liability set forth in Section 402A of the Restatement (Second) of Torts. *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1271-72 (5th Cir. 1974). Although the Fifth Circuit and the Texas Supreme Court have not ruled on this issue, both parties agree Texas courts have applied Comment k to exempt prescription drugs from strict liability under a design defect theory. *See e.g., Hackett v. G.D. Searle & Co.*, 246 F.Supp.2d 591, 595 (W.D. Tex. 2002) (granting summary judgment to defendants on plaintiff's design defect claim in context of prescription drugs; holding under Texas law and Comment k defendants can only be held strictly liable if drug not properly prepared or marketed, or accompanied by proper warnings).

Accepting the Complaint's well-pleaded allegations as true, and liberally construing it in Plaintiff's favor, the Court finds Plaintiff's Complaint contains sufficient factual matter to state a facially plausible strict-liability-design-defect claim. *See Iqbal*, 556 U.S. at 678 (standard of review); *Reyes*, 498 F.2d 1264, 1272-74 (plaintiff must prove: 1) product was defective; 2) the defect existed when the product left defendant's hands; 3) due to the defect, the product was unreasonably dangerous to the user (plaintiff); 4) plaintiff suffered injury; and 5) the defect was proximate cause of plaintiff's injuries). Indeed, as noted by Plaintiff, Defendants have not

asserted the Complaint's allegations insufficiently plead the requisite elements; but instead assert the claim is barred by Comment k.

The Court finds Defendants' Comment k argument is prematurely brought in their Motion to Dismiss. "Basically, Section 402A subjects to liability the seller or manufacturer of a product sold 'in a defective condition unreasonably dangerous' to an ultimate user or consumer whose person or property is physically harmed by the product." *Reyes*, 498 F.2d at 1272. The design defect claim's "unreasonably dangerous" inquiry involves a two-step analysis to evaluate the possible liability of a manufacturer for injuries caused by its inevitably hazardous product: 1) whether the product is so unsafe that marketing at all is "unreasonably dangerous per se"; and 2) if not, whether the product has been introduced into the stream of commerce with insufficient safeguards and is thereby "unreasonably dangerous as marketed." *Id.* at 1273. The first prong of the inquiry involves a balancing process in which the product's utility is weighed against the potential harmful effects caused by its introduction into commerce. *Id.* Only if the product is determined not "unreasonably dangerous per se" does the analysis proceed to the "unreasonably dangerous as marketed" inquiry, at which point Comment k becomes applicable. *Id.* at 1273-75. *See also Gerber v. Hoffman-La Roche, Inc.*, 392 F.Supp.2d 907, 922 (S.D. Tex. 2005) ("Under Comment K, a prescription drug is unreasonably dangerous in design if it is not 'accompanied by proper directions and warning.'"). Because the prerequisite "unreasonable dangerous" determination involves weighing of evidence, consideration of the applicability of Comment k's bar to Plaintiff's strict liability design defect claim is not appropriate in a motion to dismiss. The Court will deny Defendants' motion to dismiss Count I – Strict Liability (Design Defect).

B. Count VI – Fraudulent Misrepresentation

Defendants argue that Plaintiff's fraud claim must be dismissed with prejudice, because its allegations do not satisfy the heightened pleading standard imposed by Federal Rule of Civil Procedure 9(b). They contend Count VI is "wholly insufficient as it does nothing more than generally allege that Wright Medical engaged in 'misrepresentations and concealment' to the public with the intent to defraud." Defendants claim the Complaint does not provide any details regarding the content of the alleged misstatements or omissions; specify when or where they were made; or identify the individuals responsible for making them.

Claims alleging fraudulent representations are subject to Rule 9(b)'s heightened pleading standard, which requires they be alleged "with particularity." Fed. R. Civ. P. 9(b). Rule 9(b) usually requires the plaintiff to identify "the who, what, when, where, and how of the alleged fraud." *Schouest v. Medtronic, Inc.*, 2014 WL 1213243 at *13 (S.D. Tex. March 24, 2014) (internal quotations and citation omitted); *see also Crest Constr. II, Inc.*, 660 F.3d at 353.

Under Texas law, the elements of fraud are: 1) a material representation was made; 2) the representation was false; 3) when made, the speaker knew the representation was false, or made it recklessly without any knowledge of the truth and as a positive assertion; 4) the speaker intended the other party should act upon the representation; 5) the other party acted in reliance on the representation; and 6) the other party was injured as a result. *Aquaplex, Inc. v. Rancho La Valencia, Inc.*, 297 S.W.3d 768, 774 (Tex. 2009). This is a case in which the alleged fraudulent misrepresentations were not made directly to Plaintiff, but to Plaintiff's physicians, who relied on the representations, and who communicated the allegedly false information to Plaintiff. Thus, the Complaint's fraud allegations are based on an "intermediary theory," which imposes liability upon companies when treating physicians rely on positive and specific false representations that

the companies' products are safe and harm results. *See Schouest*, 2014 WL 1213243 at *13; *Crocker v. Winthrop Lab., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429, 433 (Tex. 1974).

Count VI of Plaintiff's Complaint alleges Defendants had actual knowledge the Wright Medical Hip Implant and Conserve Cup were defective in that the device created an unreasonably high risk of serious injury and complications when implanted and used as directed. Count VI further alleges that, despite Defendant's actual knowledge of complaints and adverse event reports received concerning the device, Defendants "knowingly and intentionally" continued to market, promote and sell their implant with no warning concerning the known high risk of serious injury and complications, so as to maximize their sales and profits at the expense of the health and safety of the public and Plaintiff. In its "General Allegations Common to All Counts," the Complaint alleges Defendants made false representations, affirmations of fact, or promises through their advertisements, labeling, detailing, marketing, and promotion of the device to healthcare professionals, the FDA, Plaintiff, and the public by representing it to be safe, effective, and fit and proper for its intended uses. Additionally, Count VI alleges all of the misrepresentations and concealment by Defendants were intentional acts specifically directed to keep safety concerns about the device from decreasing the sales of the device and were undertaken with the intent that Plaintiff and her physicians would rely upon them; and with the intent of defrauding and deceiving Plaintiff, to induce and encourage the sale of the device. Plaintiff's Complaint further alleges that Plaintiff relied upon, and was induced by Defendants' misrepresentations, omissions, and active concealment of the danger of serious and permanent the Wright Medical Hip Implant and Conserve Cup, and that she suffered personal injuries, economic and non-economic damages, including pain and suffering, as a result of Defendants' fraudulent misrepresentations and omissions concerning the dangers of the device.

Plaintiff asserts the Complaint's fraudulent misrepresentation allegations satisfy all element of fraud, as it alleges Defendants: 1) advertised and sold the Wright Medical Hip Implant with the implication it could be implanted in patients, including Plaintiff; 2) acted with gross negligence and willful and wanton disregard for the safety of the general public and Plaintiff; 3) had actual knowledge the device was defective, in that it created an unreasonably high risk of serious injury and complications when implanted and used as directed; and 4) despite having actual knowledge of the implant's potential problems, still proceeded to knowingly and intentionally market, promote, and sell the implant so as to maximize their sales and profits at the expense of the public's and Plaintiff's health and safety. In the event the Court should find Plaintiff's Complaint insufficiently pleads the fraudulent misrepresentation claim, however, Plaintiff seeks leave to amend her pleading to add additional facts or allegations.

When faced with a similar Rule 9 challenge to a Texas state law fraudulent misrepresentation claim, a district court in the Southern District of Texas determined the efficient course was to allow the plaintiff one opportunity to amend her complaint. *Schoest*, 2014 WL 1213243 at *14. "Judicial economy would be ill-served if the Court were to engage in the labor-intensive process of scrutinizing the specific allegations at this point, find them insufficient, and then follow the usual pattern of allowing the plaintiff at least one opportunity to replead." *Id.* The Court will give Plaintiff the opportunity to replead her fraud claim (Count VI) before engaging in a Rule 9(b) analysis. Should Wright Medical Group thereafter believe the amended complaint's fraudulent misrepresentation claim still is insufficiently pled, they may file another Rule 12 motion.

V. CONCLUSION

Accordingly,

IT IS HEREBY ORDERED that "Defendants Wright Medical Technology, Inc. and Wright Medical Group, Inc.'s Motion to Dismiss Counts I, VI, VII, and VIII of Plaintiff's Complaint" [ECF No. 5] is **GRANTED in part** and **DENIED in part**. Counts VII and VIII are **DISMISSED with prejudice**. Plaintiff will be given the opportunity to replead her fraudulent misrepresentation claim (Count VI). Plaintiff's amended complaint shall be filed within thirty (30) days of entry of this Order. In all other respects, Defendants' Motion is denied.

Dated this 28th day of April, 2014.

E. RICHARD WEBBER
SENIOR UNITED STATES DISTRICT JUDGE